REMARKS

Status of the Claims

Claims 1, 3, 7-12, 15-26, and 33 were pending and under consideration for purposes of the instant Office Action. Claims 2, 4-6, and 13-14 were previously canceled, and claims 27-32 were previously withdrawn. Claim 1 is currently amended, and claim 33 has been canceled in this response. Accordingly, Claims 1, 3, 7-12, and 15-26 remain for reconsideration, as amended.

Claim 1 has been further amended to more particularly recite the configuration of the claimed tablet according to the subject invention. Specifically, Claim 1 now recites that the claimed tablet has bottom active segment, which is scored, and a top inactive segment. Applicants respectfully submit that the amendments are supported by the specification and that no new matter has been added.

Support for the current amendments is found in the specification, e.g., in the drawings which illustrate the scored bottom segment, and the accompanying text describing the drawings at pages 21-24. Support is additionally provided at page 10, line 20, and is further discussed throughout the specification, including the Examples, beginning at page 12. Reconsideration of claims 1, 3, 7-12, 15-26, and 33, as amended, is respectfully requested in view of the further amendments to the claims submitted in this Reply.

Applicants thank the Examiner for the careful consideration of the previous amendments and accompanying remarks; the consequent withdrawal of the previous obviousness rejections is gratefully acknowledged. Applicants further acknowledge the acceptance of the Information Disclosure Statement submitted April 20, 2011.

A new objection to the claims, and new rejections under 35 USC 102(b) and 35 USC 103(a) were presented in the instant Office Action. These rejections are discussed below in view of the newly amended claims.

Claim Objections

Claims 17 and 33 were objected to for being substantially identical and presenting a double-patenting issue if allowed. Claim 33 has now been canceled and the objection is therefore moot. Reconsideration and withdrawal of this objection is respectfully requested.

Rejections under 35 USC 102(b)

Claims 1, 3, 7-12, 15-26, and 33 stand rejected as being anticipated under 35 USC 102(b) over Hess (CH648754), an English translation of which was provided by the applicant. This rejection is respectfully traversed.

As now claimed, the subject invention is directed to a tablet having a bottom layer containing an active drug, wherein the bottom active layer is scored, and a top inactive segment. By contrast, Hess teaches a layered tablet having, in each instance, a score in the top layer of the tablet. Because Hess does not teach a tablet having a bottom active layer which is scored, and a top inactive layer which is not scored, the cited reference cannot anticipate the claimed invention. Reconsideration and withdrawal of the anticipation rejection under 35 USC 102(b) is respectfully requested.

Rejections under 35 USC 103(a)

Claims 10, 16, and 21-26 further stand rejected as being unpatentable under 35 USC 103(a), citing Hess (CH648754), in view of Schmidt (US 4,786,507). Applicants respectfully traverse.

The Office Action identifies Hess as "not expressly teach[ing] a granulation that does not contain a drug." For clarification, applicants believe that this statement, though favoring the applicants, is not completely accurate. At page 4 of the translated CH648754, Hess recites that "Figure 1 shows a tablet … [wherein the active] layer can be S2, also as placebo layer present." Applicant believes this statement provides for a granulation that does not contain a drug. However, the S2 layer is the bottom layer and is distinct from the subject invention, which claims the inactive granulation in the top layer.

In addition, the bottom (S2) layer is not described in Hess, nor shown in any of the drawings of Hess, as being scored when only one of the layers is scored. Thus, Hess only describes a bi-layer tablet having a *bottom* layer that is inactive, and where that bottom inactive layer is only scored if the top layer is also scored. Hess does not teach or suggest a bottom *active* layer being scored and a top inactive layer which is not scored, as claimed.

Applicants have discovered that the bottom active layer must be scored in order to arrive at the tablet as claimed for the subject invention. A fully functional tablet of the subject invention is formed having a bottom active layer which is tamped prior to disposition of the top inactive layer. A scored top layer requires that the embossing is on the top tablet punch. However, providing an embossed top punch precludes tamping because the tamping step, using an embossed top punch, will necessarily form an undesired indentation in the top face of the bottom layer.

The indentation formed by the embossed top punch is then filled in when the second, inactive granulation (the top layer) is disposed onto that first layer, resulting in an uneven or un-level interface between the layers. The resulting uneven interface prevents separation of the bottom active layer into discrete active segments that are breakable through the score with minimal, if any, exposed surface area of the active.

As Dr. David Beach explains in his Rule 132 Expert Declaration, attached, Hess does not teach or suggest a tablet of the subject invention which has a bottom active layer, which is scored to form discrete unitary segments from the bottom layered granulation, and a top inactive layer. Moreover, Dr. Beach attests that Hess describes a tablet that cannot function in accordance with the subject invention, and is not operable as described in the Hess reference. The details of Dr. Beach's expert declaration are summarized below:

First, Hess describes scoring of the top layer, which requires an embossed top punch. The subject invention claims a tablet having a score on the bottom layer, i.e., using a bottom punch or die which is embossed for scoring. The bottom-scored layer, in accordance with the subject invention, allows for tamping of the first layer and formation of a level top surface for that layer without deformation (indentation) by an embossing on the top punch.

Hess fails to describe tamping at all, which reinforces the applicants' assertion regarding the failure of tamping the initial (bottom) layer. This omission from the description in Hess is clearly due to the first layer of a tablet described by Hess being unable to be tamped using an embossed top punch.

Second, the indentation formed by an embossed top punch is filled in by the second layer, resulting in incomplete separation of the scored active layer and a "bulged" interface between the active and inactive layers. This incomplete separation and bulged interface results in increased exposed surface area at the break plane, which can alter the release profile of a controlled release or matrix tablet, as compared to its profile as a whole tablet. Dr. Beach points out the Hess reference, itself, presents data showing the failure of the Hess tablets to maintain equivalent release profiles when broken, as compared to the release profiles exhibited by the whole tablets.

Third, Hess describes and shows a tablet having a band around its perimeter, forming a flat side face. The flat side face of the band is inconsistent with coating of the tablets as described by Hess because the flat face can result in adherence of those surfaces during the coating process, and "twinning" of the tablets when coatings are applied.

Based on these differences between the subject invention and Hess, applicants respectfully submit that Hess does not provide any teaching or suggestion of the subject invention as distinctly claimed. Nor is there any suggestion in Hess to modify its teaching to arrive at the subject invention. Accordingly, Hess, taken alone, is believed to clearly fail in meeting the requirements for making obvious the claimed invention.

The citation of the secondary reference, Schmidt (US 4,786,507), does not cure the defects of Hess. Schmidt is cited for its description of a placebo layer, an element that was erroneously stated in the Office Action to be absent from Hess. However, even with the Schmidt reference, there is no teaching or suggestion of a tablet comprising a bottom active layer that is scored to provide unitary segments in the active layer, and a top inactive layer that is not scored.

Moreover, with regard to tablet division, the Schmidt patent, at col. 3, lines 11-24, mentions only the desire to maintain the tablet's capability to be divided, as in conventional tablets. Schmidt does not mention dividing the tablet through a score, nor does Schmidt describe the formation of unitary segments in the active layer to facilitate such division, as is expressly claimed for the subject invention.

Schmidt also refers to, at col. 3, lines 49-64, the layering process of a bi-layer tablet by disposing (first) an inactive layer, followed by disposing (second) an active layer – a process diametrically opposed to the tableting process steps forming the claimed tablets, which involves first disposing the active layer, and then (second) the inactive layer. There is no mention in Schmidt of scoring the active (top) layer to form unitary segments because the first composition is tamped before layering of the second composition. (See "compressing it slightly," at col. 3, lines 55-56.) Thus, performing the procedure described in Schmidt "in reverse" (col. 3, lines 60-61) would also necessarily omit scoring.

Accordingly, there is no reasonable expectation of successfully arriving at the subject tablets by combining Schmidt with Hess because combining Hess and Schmidt fails to teach or suggest a bottom active layer, which is scored, and a top inactive layer. Applicants discovered that, in producing a tablet configured as claimed, and having the divisibility advantages as described, there is a need to provide the bottom active layer as the scored layer. Neither Hess nor Schmidt, taken alone or in combination, would lead a person of ordinary skill in the art to the tablets as claimed and therefore would not have made obvious the subject invention.

Reconsideration and withdrawal of the obviousness rejection citing Hess in combination with Schmidt, is respectfully requested.

Finally, claim 18 is rejected under 35 USC 103(b) as being unpatentable over Hess (CH648754) in view of Schmidt (US 4,786,507), and further in view of Nesselroad, III (US 2004/0167207). The deficiencies of the teaching of Hess and the failure of Schmidt to cure those deficiencies are discussed above and incorporated by reference for purposes of this further rejection. The reference of Nesselroad further fails to cure the deficiencies of Hess and Schmidt taken alone or together.

Nesselroad is cited for its disclosure of using warfarin as an active pharmaceutical ingredient, or drug, in a tablet – an element not expressly disclosed in Hess of Schmidt. However, there is no teaching or suggestion in Nesselroad of a warfarin-containing tablet comprising a bottom active layer that is scored to provide unitary segments in the active layer, and a top inactive layer that is not scored. Thus, the deficiencies of Hess and Schmidt are not cured by Nesselroad and the combination of these references fails to make obvious the claimed invention.

Withdrawal of this obviousness rejection citing Hess in combination with Schmidt and/or Nesselroad, is also respectfully requested upon reconsideration.

Applicants believe the subject claims, as amended, are now in condition for allowance, and respectfully request that a Notice of Allowance be issued for the instant application.

Should further information or clarification be required on any of these matters, applicants invite the Examiner to contact the undersigned at the address or phone/fax number provided below.

Respectfully submitted,

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